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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,952	08/28/2003	Kenju Miura	58777.000013	7207

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/649,952	**Applicant(s)** MIURA ET AL.	
	Examiner Bridget E. Bunner	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *07 September 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *16-37*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 3. NOTE: The amendments to claims 16, 19, 20 and submission of new claims 39-40 would raise new issues under 35 U.S.C. § 112, second paragraph for claims 16, 19, 20, 26-33, 37-49. Specifically, in claims 20 and 40, there is no step in the claims that hematopoietic progenitor cells are expanded, as required by the preamble. Additionally, in claims 16, 19, 20, and 39-40 the term "promoter" is intended by the claims to mean "promoter of growth /differentiation", while the accepted meaning of "promoter" is "a DNA sequence at which RNA polymerase binds and initiates transcription". The term is indefinite because the specification does not clearly redefine the term.

If the amendment of 07 September 2006 had been entered, the rejection of claims 20 and 24 under 35 U.S.C. § 112, second paragraph, would have been withdrawn.

If the amendment of 07 September 2006 had been entered, the rejection of all pending claims under 35 U.S.C. § 112, first paragraph (scope of enablement) would have been maintained. First, claims 16 and 39 still read upon the administration of the Cofilin protein to a subject. As discussed in the previous Office Actions, the prior art and the specification of the instant application do not teach the administration of any Cofilin protein to any subject for the promotion of growth and differentiation of hematopoietic stem cells or progenitor cells. Undue experimentation would be required of one skilled in the art to determine the route of administration of the protein, as well as quantity and duration of treatment. Applicant did not specifically address this issue in the response of 07 September 2006. Second, the newly amended recitation of "Cofilin including the amino acid sequence depicted by SEQ ID NO: 1" has been broadly interpreted by the Examiner as encompassing variants, fragments, derivatives of SEQ ID NO: 1 as well as larger sequences that incorporate SEQ ID NO: 1. As discussed in the previous Office Actions, the specification also does not teach functional and structural characteristics of the polypeptide variants, fragments, and derivatives recited in the claims. The broad brush discussion of making and screening for Cofilin variants does not constitute a disclosure of a representative number of members. (Please note that this issue could be overcome by amending the claims to recite, for example, "...comprising the Cofilin protein of SEQ ID NO: 1".)

If the amendment of 07 September 2006 had been entered, the rejection of all pending claims under 35 U.S.C. § 112, first paragraph (written description) would have been maintained. Specifically, the newly amended recitation of "Cofilin including the amino acid sequence depicted by SEQ ID NO: 1" has been broadly interpreted by the Examiner as encompassing variants, fragments, derivatives of SEQ ID NO: 1 as well as larger sequences that incorporate SEQ ID NO: 1. As discussed previously, the description of one Cofilin polypeptide species (SEQ ID NO: 1), is not adequate written description of an entire genus of functionally equivalent polypeptides which incorporate all variants, fragments, and derivatives or an entire genus of methods of using those variants, fragments, and derivatives. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The skilled artisan cannot envision the Cofilin proteins of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method.

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER